



NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[NRC-2023-0086]

Draft Regulatory Guide: Release of Patients Administered Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft regulatory guide (DG), DG-8061, "Release of Patients Administered Radioactive Material." This DG is proposed Revision 2 to Regulatory Guide (RG) 8.39 of the same name. This proposed revision provides licensees with methods that are acceptable to the NRC for the release of patients after a medical procedure involving the administration of unsealed byproduct material, such as radiopharmaceuticals, or implants that contain radioactive material.

DATES: Submit comments by **[INSERT DATE 60 DAYS AFTER DATE OF**

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the **Federal rulemaking website**:

- **Federal rulemaking website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2023-0086**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individuals listed in the "For Further Information Contact" section of this document.

- **Mail comments to:** Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Kathrine Tapp, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-0236; email: Kathrine.Tapp@nrc.gov, or Brian Allen, Office of Nuclear Regulatory Research, telephone: 301-415-8402; email: Brian.Allen3@nrc.gov, or Rigel Flora, Office of Nuclear Regulatory Research, telephone: 301-415-3890; email: Rigel.Flora@nrc.gov, or Harriet Karagiannis, Office of Nuclear Regulatory Research, telephone: 301-415-2493; email: Harriet.Karagiannis@nrc.gov. All are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2023-0086** when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2023-0086**.

- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the **Federal rulemaking website** (<https://www.regulations.gov>). Please include Docket ID **NRC-2023-0086** in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's "Regulatory Guide" series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

The DG, entitled “Release of Patients Administered Radioactive Material,” is temporarily identified by its task number, DG-8061. This DG-8061 is a proposed Revision 2 to RG 8.39 (ADAMS Accession No. ML21230A318).

This proposed Revision 2 provides: (1) information for the administered activity and measured dose rate thresholds to demonstrate compliance for commonly used radionuclides, (2) calculational methodologies to accommodate threshold modifications for patient-specific exposure situations with modifying factors for biokinetics, occupancy, geometry, and attenuation based on patient-specific information, (3) calculations assuming unity for the occupancy factor if patient-specific information is not known, to avoid underestimating exposure, (4) flexibility for emerging radiopharmaceuticals that could be used for diagnostic or therapeutic purposes, (5) radiopharmaceutical activity thresholds for patients who may continue breastfeeding an infant or child after administration of radioactive material, with recommendations for breastfeeding interruption times for many typical administered medical dosages, and (6) a new section on “Sources Separated from the Patient.”

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML21230A326). The staff develops a regulatory analysis to assess the value of issuing or revising a regulatory guide as well as alternative courses of action.

As noted in the *Federal Register* on December 9, 2022 (87 FR 75671), this document is being published in the “Proposed Rules” section of the *Federal Register* to comply with publication requirements under 1 CFR chapter I.

III. Backfitting, Forward Fitting, and Issue Finality

As discussed in the “Implementation” section of DG-8061, the NRC does not intend or approve any imposition of the guidance in this draft regulatory guide. Backfitting and issue finality considerations do not apply to licensees or applicants when performing activities under part 35 of title 10 of the *Code of Federal Regulations* (10 CFR). Therefore, the NRC has determined that its backfitting and issue finality regulations would not apply to this draft regulatory guide, if ultimately issued as Revision

2 to RG 8.39, because the draft regulatory guide does not include any provisions within the scope of matters covered by the backfitting provisions in 10 CFR parts 50, 70, 72, or 76 or the issue finality provisions of 10 CFR part 52.

IV. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at <https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html>. Suggestions will be considered in future updates and enhancements to the "Regulatory Guide" series.

Dated: April 17, 2023.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief,

Regulatory Guide and Programs Management Branch,

Division of Engineering,

Office of Nuclear Regulatory Research.

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